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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,453	10/11/2005	Orhan Kaya Koksalan	027564-00004	4919

4372 7590 10/03/2008

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EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
10/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary	Application No.	Applicant(s)	
	10/528,453	KOKSALAN ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *1-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0305*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Requirement for Information*.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10528453	10/11/05	KOKSALAN ET AL.	027564-00004

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EXAMINER
Diana B. . Johannsen

ART UNIT	PAPER
1634	20080922

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Requirement for information under 37 CFR 1.105.

1. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.
2. As evidenced by the abstract cited in a rejection under 35 USC 103 in the attached Office action (Kocagoz, T. and Koksalen, K., Abstracts of the General Meeting of the American Society for Microbiology 101:205 [May 20-24, 2001]), Applicants made an oral presentation describing a method and product that suggest the claimed invention at a scientific meeting more than 1 year before the effective filing date of the instant application. As discussed in MPEP 2128.01, written copies of such presentations may constitute "printed publications" qualifying as prior art if disseminated without restriction, and publically displayed documents can similarly constitute prior art if they have been made "publically accessible" at an event such as a scientific meeting.
3. Accordingly, in response to this requirement, please provide answers to each of the following interrogatories eliciting factual information, and provide copies of the materials requested in accordance with the instructions noted below:
a. Were any written copies of the presentation noted above disseminated without restriction? If replying in the affirmative to this interrogatory, please also provide a copy of the material distributed.
b. What documents were publically displayed at the Meeting referenced above (i.e., please provide a copy of any publically displayed materials)? Additionally, please provide a description of the manner and duration of the display sufficient to allow the examiner to determine whether the materials were publically accessible.
4. This information is being required because it is necessary for the examiner to review any materials as noted in 3 a) or b), above, in order to determine whether those materials constitute prior art under 35 USC 102(b) that must be applied against applicants' claims, and because it is not possible for the examiner to independently determine what materials may have been provided and/or displayed, and in what manner.
5. The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.
6. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.
7. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634

DETAILED ACTION

1. This application is a 371 of PCT/TR03/00082, filed September 26, 2003. The international search report and international preliminary examination report for the PCT application are present in the instant application file and have been considered by the examiner. It is noted that a translation of the foreign priority document (Turkish application 2002 02252, filed September 26, 2002) has not been provided.

Election/Restrictions

2. Applicant's election with traverse of Group II, claims 8-14, in the reply filed on August 1, 2008 is acknowledged. The traversal is on the ground(s) that "the burden on the Patent Office to examine both groups of claim together is less than the burden on Applicants to prosecute the groups of claims separately." This is not found persuasive because the instant application is a 371 application in which restriction was required under 35 USC 121 and 372 because Groups I-II lack unity of invention under PCT Rule 13.2 and thus do not relate to a single general inventive concept under PCT Rule 13.1. Search burden is not one of the criteria considered with respect to restriction of a 371 application (and further, to the extent that search burden might be relevant in the present case, applicants have not provided any reasons why an undue burden is believed to be lacking). Unity of invention is lacking for the reasons given in the requirement of July 1, 2008, and applicant's remarks do not traverse the lack of unity or otherwise address the actual basis of the restriction. Accordingly, applicants' arguments are not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 1, 2008.

Information Disclosure Statement

4. The information disclosure statement filed March 18, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It is noted that the Brunello et al reference has been indicated as having been considered because the reference was previously cited by the examiner. However, the references WO 01/31061 A and Philipp et al have not been considered because copies of the references were required but not provided. it is noted that the Form PCT/DO/EO/903 mailed to applicant on May 27, 2008 did not indicate that the cited references were present in the application file (see MPEP 609.03).

Drawings

5. The drawings are objected to because the text of each of Figures 1-2 is blurry and not sufficiently clear for printing purposes. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be

labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The substitute specification filed August 30, 2005 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: the marked up specification does not show all changes relative to the previous version of the specification (see MPEP 714). In particular, it is noted that the specification was amended March 18, 2005 to add a cross reference section which is not present in the specification filed August 30, 2005 (i.e., the cross reference has been deleted without appropriate markings). **Accordingly, a new substitute specification correctly illustrating all changes is required. Applicant is also reminded that the specification was amended on April 11, 2008 to add SEQ ID NOs on page 5, and that this amendment has been entered.**

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-13 are indefinite because it is not clear how the method steps of independent claim 9 relate to each other and to the objective of producing "the molecular size marker of claim 8." For example, the language of the claim does not make clear what is being amplified in step b) (i.e., is this step actually performed on the DNA of step a)?), what is being cloned in step d) (i.e., the amplification products of step

c, or something else?). Further, the language of the claim does not make clear how the restriction digestion of step f) relates to or results in the production of a marker. Accordingly, the language of claim 9 should be amended to clarify how the various steps relate to one another and result in production of the recited "molecular size marker."

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step or steps indicating how the stated objective of "determining the size of restriction fragments." The claim as presently written is drawn to a "method" but only recites a product, without giving any indication as to how the product is actually employed, and how the required "determining" is accomplished. Accordingly, clarification is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 8-14 rejected under 35 U.S.C. 103(a) as being unpatentable over Kocagoz et al (Abstracts of the General Meeting of the American Society for Microbiology 101:205 [May 2001]) in view of Brunello et al (Journal of Clinical Microbiology 39(8):2799-2806 [Aug 2001]).

Kocagoz et al disclose a method for producing a "molecular weight marker that facilitates rapid identification of mycobacteria to species level by restriction fragment length polymorphism analysis of hsp65 gene" (see title and entire abstract). The method disclosed by Kocagoz et al comprises steps of selecting "mycobacterial species that produced distinct restriction fragments," amplifying "their hsp65 by PCR," cloning the amplification products into a vector, purifying the resulting plasmids, and digesting with BstEII and HaeIII the "amplified hsp65 from clones belonging to various selected species of mycobacteria" to produce "molecular weight markers with all possible fragments exactly matching the ones that can be obtained" during methods of PCR and restriction enzyme analysis (PRA) of hsp65 that are used for mycobacterial species detection (see entire abstract). Thus, Kocagoz et al suggest all of the steps of instant claim 9, as well as the use of the enzyme of dependent claim 13 (HaeIII), but do not teach the particular fragment sizes of claims 8 or 10, the mycobacterial species of claim 11, or the primers of claim 12.

Like Kocagoz et al, Brunello et al disclose PRA of hsp65 to achieve detection of mycobacterial species (see entire reference). Brunello et al disclose the use in their methods of the primer pair recited in applicants' claim 12 (see description of "PCR for PRA" at page 2799, right column-2800, left column). Brunello et al disclose PCR amplification using this primer pair and subsequent HaeIII digestion in typing a variety of different mycobacteriae, including species that produce fragments either identical in size or no more than 1 nucleotide different in size as compared to the list of fragment sizes of claims 8 and 12 (see Tables 2 and 3). Brunello et al teach that fragments analyzed during PRA of hsp65 exhibit different lengths depending on the type of method used in measuring the fragments (e.g., agarose vs. polyacrylamide electrophoresis); for example, Brunello et al report groups of fragments that exhibit differences of 5 base pairs and groups that exhibit differences of 10 base pairs, etc. (see, e.g., pages 2801-2803). Accordingly, given that applicants' claims broadly encompass any possible method of measuring fragment sizes, the fragment sizes taught by Brunello et al meet the requirements of the claims. It is further noted that Brunello et al disclose all the species of claim 11 with the exception of M. gallinarum, and that claim 11 requires only one of the species recited in the claim.

In view of the teachings of Brunello et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Kocagoz et al so as to have employed any of the species taught by Brunello et al (which species include several of those of claim 11), and thereby to have produced a DNA molecular size marker meeting the requirements of claim 8 (and 10). Kocagoz

et al teach that they analyzed 33 different mycobacterial species and selected species that "produced distinct restriction fragments" for use as markers. Accordingly, the teachings of Kocagoz et al would have motivated one of ordinary skill to have selected any such species from those of Brunello et al to similarly achieve the predictable result of producing such a marker. As a subset of the markers produced in this manner would comprise fragments of the sizes set forth in claims 8 and 10, the combined teachings of Kocagoz et al and Brunello et al suggest the claimed invention.

With further regard to claim 12, it would also have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Kocagoz et al so as to have employed the particular primers taught by Brunello et al. As Brunello et al disclose that these primers may be used successfully in the PRA analysis of numerous mycobacteria species, an ordinary artisan would have been motivated to have made such a modification for the advantage of and to achieve the predictable result of successfully amplifying the mycobacterial nucleic acids required to produce the markers suggested by Kocagoz et al in view of Brunello et al.

Finally, with regard to claim 14, it is noted that the claim as presently written appears to only require the product of claim 8, which product is suggested by Kocagoz et al in view of Brunello et al for the reasons given above. However, to the extent that the claim may in fact be drawn to a method that requires steps to achieve determining the sizes of HaeIII fragments during electrophoretic analysis of hsp65 by PCR-REA, as Kocagoz et al teach that their markers were designed for use in such methods, the

combined teachings of Kocagoz et al and Brunello et al specifically suggest such an invention.

Conclusion

12. This Office action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634

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